110TH CONGRESS
1ST SESSION

S. _____

To amend the Public Health Service Act to improve and secure an adequate supply of influenza vaccine.

IN THE SENATE OF THE UNITED STATES

_____ introduced the following bill; which was read twice and referred to the Committee on _____

A BILL

To amend the Public Health Service Act to improve and secure an adequate supply of influenza vaccine.

Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled,

SECTION 1. SHORT TITLE.

This Act may be cited as the ''Influenza Vaccine Security Act of 2007''.

TITLE I—MARKET GUARANTEES

SEC. 101. AMENDMENT TO THE PUBLIC HEALTH SERVICE ACT.

Title XXI of the Public Health Service Act (42 U.S.C. 300aa–1 et seq.) is amended by adding at the end the following:

"Subtitle 3—Influenza Vaccine Security

"SEC. 2141. ESTABLISHMENT OF AN INFLUENZA VACCINE TARGET AND STOCKPILE.

''(a) ANNUAL TARGET.—The Secretary, in consultation with the Advisory Committee on Immunization Practices to the Centers for Disease Control and Prevention (referred to in this subtitle as the 'Advisory Committee'), shall determine an annual production target for influenza vaccine, based on the recommendations of the Advisory Committee. Based on such target, the Secretary, acting through the Centers for Disease Control and Prevention, shall coordinate with the private market to encourage the production of such vaccine in amounts that will meet the annual target.

''(b) STOCKPILE.—Prior to the start of each annual influenza season (as determined by the Secretary), the Secretary is authorized to purchase and store from multiple manufacturers an amount not to exceed 10 percent

of the total amount of influenza vaccine, including one or more active vaccine antigen ingredients in bulk or filled form, that is designated for production by the Advisory Committee for placement in the strategic national stockpile under section 121 of the Public Health Security and Bioterrorism Preparedness and Response Act of 2002 (referred to in this subtitle as the 'strategic national stockpile'). Such vaccine shall be held in reserve to be used in the event of a vaccine shortage in a given influenza season. The Secretary shall coordinate with the manufacturers involved to ensure that reserving amounts of vaccine for the stockpile does not interfere with the early season delivery or early season administration of vaccine to high priority populations (as defined by the Advisory Committee on Immunization Practices and the Centers for Disease Control and Prevention) (referred to in this subtitle as 'high priority populations').

"SEC. 2142. VACCINE BUYBACK PROGRAM.

''(a) IN GENERAL.—The Secretary shall establish an influenza vaccine buyback protocol under which the Secretary may enter into buyback contracts with manufacturers of influenza vaccine to purchase such manufacturers' excess stocks of influenza vaccine so long as such vaccine has been manufactured in accordance with the rec-

ommendations of the Advisory Committee for the production of seasonal influenza vaccine.

''(b) MANUFACTURERS.—The Secretary shall have the discretion to award buyback contracts under subsection (a) to several influenza vaccine manufacturers in a manner consistent with the goal of providing stability in the influenza vaccine market, as long as the Federal Government purchases not more than 50 percent of the excess influenza vaccine stock of any single manufacturer at market price.

''(c) COOPERATION WITH MANUFACTURERS, DISTRIBUTORS, AND WHOLESALERS.—As a condition of participation in the buyback program under this section, the Director of the Centers for Disease Control and Prevention shall work in cooperation with influenza vaccine manufacturers and wholesalers and distributors within the chain of custody from factory to health care institution or health care providers to share pertinent information that will allow for the tracking of influenza vaccine, maximize the delivery and availability of influenza vaccines to high priority populations, and ensure that influenza vaccine is delivered on an equitable basis, particularly in times of vaccine shortages.

''(d) CONFIDENTIALITY.—The information submitted to the Centers for Disease Control and Prevention or its

contractors, if any, under subsections (c) and (d) shall remain confidential in accordance with the exception from the public disclosure of trade secrets, commercial or financial information, and information obtained from an individual that is privileged and confidential, as provided for in section 552(b)(4) of title 5, United States Code, and subject to the penalties and exceptions under sections 1832 and 1833 of title 18, United States Code, relating to the protection and theft of trade secrets, and subject to privacy protections that are consistent with the regulations promulgated under section 264(c) of the Health Insurance Portability and Accountability Act of 1996. None of such information provided by a manufacturer, wholesaler, or distributor shall be disclosed without its consent to another manufacturer, wholesaler, or distributor, or shall be used in any manner to give a manufacturer, wholesaler, or distributor a proprietary advantage over its competitors.

''(e) ABILITY TO NEGOTIATE.—The Secretary shall have the ability to negotiate, on a case-by-case basis, the submission of information under subsection (c), as long as the information provided will achieve the goals of tracking of the influenza vaccine, maximizing the delivery and availability of influenza vaccines to high priority populations, and ensuring that influenza vaccine is delivered

on an equitable geographical basis, particularly in times of vaccine shortages.

''(f) NOTICE.—

''(1) IN GENERAL.—For purposes of maintaining and administering the supply of vaccines described under subsection (a), the Secretary shall by contract require that a manufacturer of a vaccine included in such supply provide not less than 12 months notice to the Secretary of a purposeful discontinuance of the manufacture of such vaccine by the manufacture of the vaccine.

''(2) REDUCTION OF PERIOD OF NOTICE.—The notification period required under paragraph (1) shall not apply in a case in which vaccine production is interrupted because of unforeseen manufacturing concerns.

''(g) USE OF VACCINE POST BUYBACK.—Following the buyback of vaccine under this section, the Secretary shall direct that any vaccine purchased in such buyback be used for the following activities:

''(1) Use in late-season mass vaccination exercises conducted in coordination with Federal, State or local agencies engaged in emergency preparedness and bioterrorism preparedness activities. Such exercises should be carried out in partnership with vol-

untary organizations working to improve emergency preparedness and bioterrorism preparedness.

''(2) Promoting and carrying out late-season vaccination through the Indian Health Service, the Public Health Service, or through other federally-funded health care providers, such as community health centers and rural health clinics.

''(3) Other activities approved by the Secretary.

''SEC. 2143. CRITICAL SUPPLY PURCHASE PROGRAM.

''(a) IN GENERAL.—The Secretary shall increase the amount of antiviral medications, N-95 respirator masks, and other protections and treatments, as determined necessary by the Secretary as they become available, to treat and prevent pandemic influenza, in the strategic national stockpile. In increasing such amounts, the Secretary shall consult with the Director of the Centers for Disease Control and Prevention and the Assistant Secretary for Preparedness and Response, to determine the amounts that are necessary to provide adequate protection to not less than the number of individual who respond to an influenza epidemic.

''(b) PEDIATRIC PROGRAMS.—The Secretary is encouraged to consult with all relevant Federal agencies and the private sector to develop and approve N-95 respirators and other protections and treatments, as determined nec-

essary by the Secretary, to treat and prevent pandemic influenza, and shall ensure that such products are represented in adequate amounts in the strategic national stockpile to provide adequate protection to pediatric populations in the United States.

''SEC. 2144. AUTHORIZATION OF APPROPRIATIONS.

''There are authorized to be appropriated such sums as may be necessary to carry out this subtitle in each of fiscal years 2008 through 2012.''.

TITLE II—FOOD AND DRUG ADMINISTRATION ASSISTANCE TO MANUFACTURERS

SEC. 201. AMENDMENT TO THE FOOD, DRUG, AND COSMETIC ACT.

Chapter IX of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 391 et seq.) is amended by adding at the end the following:

''SEC. 909. PROVISIONS RELATED TO THE EMERGENCY ACQUISITION OF VACCINES.

''(a) IN GENERAL.—

''(1) INCREASED COMMUNICATION.—The Food and Drug Administration shall carry out activities to increase communication between the agency and the scientific community regarding vaccine development and regulation, including participation in con-

ferences on the science related to infectious diseases, influenza, biologic manufacturing, and other issues as determined appropriate by the Director of the Center for Biologics Evaluation and Research.

''(2) REGULATORY ROADMAP.—The Commissioner, in consultation with the Director of the Centers for Disease Control and Prevention, the Secretary, and other agencies or participants as determined appropriate by the Secretary, shall develop a regulatory roadmap to address the following issues surrounding emergency use authorization of influenza vaccine, as determined by the Secretary during a public health emergency involving an actual or imminent outbreak of naturally occurring or engineered seasonal influenza:

''(A) Policies for the emergency use authorization of influenza vaccine that is produced and sold in other countries so that such vaccine may be imported into the United States by the United States government during a vaccine shortage.

''(B) Policies for the facilitation of the distribution of any such vaccine imported into the United States during a vaccine shortage, including the interstate transportation, allocation

and equitable distribution of vaccine among high priority populations (as defined by the Advisory Committee on Immunization Practices and the Centers for Disease Control and Prevention) during an emergency use situation.

''(C) Policies for the communication and coordination of a response to an emergency use authorization with State and local health departments, including guidelines for notification of such entities in such situations.

''(D) Policies for the emergency use authorization of vaccines that are in clinical development in both the United States and other countries, including clarification of IND protocols for such vaccines, particularly those using new vaccine development technologies.

''(3) CONSULTATION.—In developing the roadmap under paragraph (2), the Commissioner shall solicit input from private and nonprofit stakeholders, including State and local health officials, and such input shall include recommendations for developing emergency use authorization guidelines that maintain the scientific and regulatory standards of the Food and Drug Administration.

''(4) STANDING ORDERS.—

''(A) DEVELOPMENT.—The Secretary shall direct the Centers for Disease Control and Prevention, in conjunction with State and local health departments and representatives of State medical boards and nursing examiners, to develop and publish a model standing order that will, at a minimum, address the need for standing orders to administer influenza vaccine in hospitals, community health centers, nursing homes, and other assisted living facilities, and by home health care providers. The Centers for Disease Control and Prevention is encouraged to expand such a model standing order to take into account—

''(i) the administration of other Medicare covered vaccines; and

''(ii) the delivery of influenza vaccine to patients in children's hospitals or other institutions serving the long-term care needs of a pediatric population, including those in a non-clinical setting.

''(B) IMPLEMENTATION.—Not less than 1 year after the publication of the standing order under paragraph (A), States shall be required

to implement such standing order in order to be eligible to receive grants under this Act.

''(C) RULE OF CONSTRUCTION.—Nothing in this paragraph shall be construed as precluding the application of State laws, so long as such laws do not restrict the implementation of this requirements of the Influenza Vaccine Security Act of 2007 (and the amendments made by such Act).

''(b) AUTHORIZATION OF APPROPRIATIONS.—There are authorized to be appropriated to carry out this section, $5,000,000 for fiscal year 2008, and such sums as may be necessary for each of fiscal years 2009 through 2012, to be made available to the Food and Drug Administration to provide the technical assistance and take advantage of the training opportunities as designated in this section.''.

TITLE III—VACCINE EDUCATION, OUTREACH, AND COORDINATION

SEC. 301. AUTHORITY OF THE NATIONAL CENTER FOR IMMUNIZATION AND RESPIRATORY DISEASES FOR COORDINATION, EDUCATION, OUTREACH, AND COMMUNICATION ACROSS HHS.

Section 2102 of the Public Health Service Act (42 U.S.C. 300aa–2) is amended—

(1) in subsection (a), by adding at the end the following:

''(10) COORDINATION OF SUPPORT.—The Director of the Center, in consultation with the Director of the National Institute for Allergy and Infectious Disease, shall—

''(A) coordinate efforts in regard to all influenza vaccine education, outreach, surveillance, and research activities within the Department in support of the goal of—

''(i) increasing overall influenza vaccination rates in the United States, particularly those of high priority populations (as defined by the Advisory Committee on Immunization Practices and the Centers for Disease Control and Prevention) and health care providers,

''(ii) increasing vaccination rates among medically underserved populations with low vaccination rates; and

''(iii) any other vaccine promotion activities as directed by the Secretary;

''(B) coordinate educational efforts under this paragraph with the National Vaccine Program Office, State and local health depart-

ments, the National Institutes of Health, and all other relevant Federal and other entities as designated by the Director; and

''(C) provide an annual report to Congress on the progress being made toward the goals described in subparagraph (A).''; and

(2) by adding at the end the following:

''(c) APPROPRIATIONS FOR COORDINATION OF INFLUENZA VACCINE OUTREACH ACTIVITIES.—There is authorized to be appropriated to carry out activities under subsection (a)(10), $2,000,000 for each of fiscal years 2008 through 2012.''.

TITLE IV—INCREASED INFLUENZA VACCINE AND OUTBREAK SURVEILLANCE ACTIVITIES

SEC. 401. TRACKING NETWORK AND DEMONSTRATION GRANTS.

Title III of the Public Health Service Act is amended by inserting after section 319B (42 U.S.C. 247d–2) the following:

''SEC. 319B–1. TRACKING NETWORK AND DEMONSTRATION GRANTS.

''(a) TRACKING SYSTEM.—

''(1) ESTABLISHMENT.—Not later than 2 years after the date of enactment of this section, the Director of the Centers for Disease Control and Prevention, in conjunction with State and local public health officials and health provider and nonprofit organizations, shall establish an electronic tracking system through which the Director and such officials can determine the amount of influenza vaccine within a 24-hour window that is available for distribution to patients, as well as the need for such vaccine on a county-by-county basis, and the progress of vaccine delivery and distribution efforts at the State and local level.

''(2) ESTIMATES.—The tracking system established under paragraph (1) shall collect estimates of the size of high priority populations (as defined by the Advisory Committee on Immunization Practices and the Centers for Disease Control and Prevention) (referred to in this section as 'high priority populations') in each county in the United States, so as to better determine where influenza vaccine resources may need to be directed in the case of an emergency.

''(3) PROVISION OF INFORMATION.—To be eligible to participate in buyback programs the vaccine

manufacturer shall provide information to the tracking system as the Director of the Centers for Disease Control and Prevention determines appropriate in accordance with subtitle 3 of title XXI.

''(4) CONFIDENTIALITY.—The information submitted to the Secretary (or a contractors, if any) under this section or under any other section of this Act related to vaccine distribution information shall remain confidential in accordance with the exception from the public disclosure of trade secrets, commercial or financial information, and information obtained from an individual that is privileged and confidential, as provided for in section 552(b)(4) of title 5, United States Code, and subject to the penalties and exceptions under sections 1832 and 1833 of title 18, United States Code, relating to the protection and theft of trade secrets, and subject to privacy protections that are consistent with the regulations promulgated under section 264(c) of the Health Insurance Portability and Accountability Act of 1996. None of such information provided by a manufacturer, wholesaler, or distributor shall be disclosed without its consent to another manufacturer, wholesaler, or distributor, or shall be used in any manner

to give a manufacturer, wholesaler, or distributor a proprietary advantage.

''(5) GUIDELINES.—The Secretary, in order to maintain the confidentiality of relevant information and ensure that none of the information contained in the systems involved may be used to provide proprietary advantage within the vaccine market, while allowing State, local, and tribal health officials access to such information to maximize the delivery and availability of vaccines to high priority populations, during times of influenza pandemics, vaccine shortages, and supply disruptions, in consultation with manufacturers, distributors, wholesalers and State, local, and tribal health departments, shall develop guidelines permitting the Department of Health and Human Services to carry out paragraphs (1) and (2) and (3).

''(b) EXPANSION OF CURRENT SYSTEMS AND ACTIVITIES.—

''(1) SURVEILLANCE SYSTEM.—Not later than 4 years after the date of enactment of this section, the Director of the Centers for Disease Control and Prevention shall upgrade and enhance the influenza surveillance system of the Centers for Disease Control and Prevention to report influenza data from

State and local health departments into the tracking system established under subsection (a)(1).

''(2) EDUCATIONAL MATERIALS.—The tracking system shall contain information to assist users in accessing influenza education, outreach, and communications tools, such as those developed and financed under the Influenza Vaccine Security Act of 2007 (and the amendments made by such Act).

''(c) DEMONSTRATION GRANTS.—

''(1) IN GENERAL.—The Director of the Centers for Disease Control and Prevention shall award demonstration grants to State and local health departments to enable such departments to enter into contract with hospitals, community health centers, long-term care facilities, physicians' offices, and health care facilities operated or funded by such departments to assist such entities in upgrading their information technology, infrastructure, and workforce in a manner that will allow such entities to improve their ability to report and track influenza vaccine dissemination.

''(2) PRIORITY.—In awarding grants under paragraph (1), priority shall be given to entities that serve high priority populations in medically underserved areas.

''(d) AUTHORIZATION OF APPROPRIATIONS.—There are authorized to be appropriated—

''(1) to carry out subsection (a), $100,000,000 for each of fiscal years 2008 through 2012, of which $500,000 for each fiscal year shall be made available to implement subsection (b)(3); and

''(2) to carry out subsection (c), $100,000,000 for each of fiscal years 2008 through 2012.''.

TITLE V—FLU VACCINE OUTREACH AND EDUCATION

SEC. 501. EDUCATIONAL EFFORTS AND GRANTS.

Title III of the Public Health Service Act is amended by inserting after section 319B–1 (as added by section 401) the following:

''SEC. 319B–2. IMMUNIZATION EDUCATIONAL EFFORTS AND GRANTS.

''(a) IN GENERAL.—The Director of the Centers for Disease Control and Prevention, in conjunction with State and local health departments, shall revise and expand the influenza-related educational materials to the Centers for Disease Control and Prevention, and facilitate the use of such materials by health care providers and patients. The Director is authorized to coordinate such educational efforts with nonprofit provider and patient advocacy groups.

''(b) INFLUENZA VACCINE EDUCATION AND OUTREACH.—

''(1) IN GENERAL.—In order to achieve an optimal balance in the influenza vaccine market, and to ensure that the recommendations of the Advisory Committee on Immunization Practices to the Centers for Disease Control and Prevention for vaccine administration are carried out to the maximum extent possible, the Director of the Centers for Disease Control and Prevention, in conjunction with State and local health departments, shall carry out influenza immunization education and outreach activities that target physicians and other health care providers, health insurance providers, health care institutions and patients, particularly those in high priority populations (as defined by the Advisory Committee on Immunization Practices and the Centers for Disease Control and Prevention) (referred to in this section as 'high priority populations').

''(2) TYPES OF ACTIVITIES.—The education and outreach activities under paragraph (1) shall include—

''(A) activities to encourage voluntary participation in influenza vaccination programs, with the goal of increasing overall influenza

vaccination rates in the United States, achieving full influenza vaccination of all high priority populations, and full use of each season's influenza vaccine supply and late season vaccination;

''(B) the provision of information on influenza prevention, including to medically underserved communities with low vaccination rates;

''(C) activities to increase the number of healthcare providers who receive influenza vaccines each year; and

''(D) other influenza educational efforts determined appropriate by the Director.

''(c) GRANTS.—The Director of the Centers for Disease Control and Prevention may award grants to State and local health departments to carry out activities to encourage individuals, particularly those from high priority populations, to seek out influenza vaccinations.

''(d) COLLABORATION.—State and local health departments that receive grants under subsection (b) are encouraged to collaborate on projects with physicians and other health care providers, health insurance providers, health care institutions, and groups representing high priority populations.

''(e) AUTHORIZATION OF APPROPRIATIONS.—In addition to any amounts otherwise available through the Sec-

retary for influenza outreach and education, there is authorized to be appropriated to carry out this section, $10,000,000 for each of fiscal years 2008 through 2012.''.